

§ 866.5580

milk, other body fluids, and tissues. Measurement of lactoferrin may aid in the diagnosis of an inherited deficiency of this protein.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 65 FR 2312, Jan. 14, 2000]

§ 866.5580 *Alpha-1-lipoprotein immunological test system.*

(a) *Identification*. An *alpha-1-lipoprotein* immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the *alpha-1-lipoprotein* (high-density lipoprotein) in serum and plasma. Measurement of *alpha-1-lipoprotein* may aid in the diagnosis of Tangier disease (a hereditary disorder of fat metabolism).

(b) *Classification*. Class II (performance standards).

§ 866.5590 *Lipoprotein X immunological test system.*

(a) *Identification*. A lipoprotein X immunological test system is a device that consists of the reagents used to measure by immunochemical techniques lipoprotein X (a high-density lipoprotein) in serum and other body fluids. Measurement of lipoprotein X aids in the diagnosis of obstructive liver disease.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 65 FR 2313, Jan. 14, 2000]

§ 866.5600 *Low-density lipoprotein immunological test system.*

(a) *Identification*. A low-density lipoprotein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the low-density lipoprotein in serum and other body fluids. Measurement of low-density lipoprotein in serum may aid in the diagnosis of disorders of lipid (fat) metabolism and help to identify young persons at risk from cardiovascular diseases.

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(b) *Classification*. Class II (performance standards).

§ 866.5620 *Alpha-2-macroglobulin immunological test system.*

(a) *Identification*. An *alpha-2-macroglobulin* immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the *alpha-2-macroglobulin* (a serum protein) in plasma. Measurement of *alpha-2-macroglobulin* may aid in the diagnosis of blood-clotting or clot lysis disorders.

(b) *Classification*. Class II (performance standards).

§ 866.5630 *Beta-2-microglobulin immunological test system.*

(a) *Identification*. A *beta-2-microglobulin* immunological test system is a device that consists of the reagents used to measure by immunochemical techniques *beta-2-microglobulin* (a protein molecule) in serum, urine, and other body fluids. Measurement of *beta-2-microglobulin* aids in the diagnosis of active rheumatoid arthritis and kidney disease.

(b) *Classification*. Class II (performance standards).

§ 866.5640 *Infectious mononucleosis immunological test system.*

(a) *Identification*. An infectious mononucleosis immunological test system is a device that consists of the reagents used to measure by immunochemical techniques heterophile antibodies frequently associated with infectious mononucleosis in serum, plasma, and other body fluids. Measurements of these antibodies aid in the diagnosis of infectious mononucleosis.

(b) *Classification*. Class II (performance standards).

[47 FR 50823, Nov. 9, 1982; 47 FR 56846, Dec. 21, 1982]

§ 866.5660 *Multiple autoantibodies immunological test system.*

(a) *Identification*. A multiple autoantibodies immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoantibodies (antibodies produced against the body's own tissues) in